

Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2003 list were published in the Federal Register in November 2003.

New Approvals

ANADA Number: 200-312

Pioneer Product: 012-559
Trade Name: Dexium™
Ingredients: Dexamethasone
Sponsor: Cross Vetpharm Group, Ltd.
Approval Date: October 20, 2003
Status: Prescription only
Route: Intravenous, intramuscular
Species: Dogs, cats, horses, and cattle
Drug Form: Liquid (solution)
Concentration: 2 milligrams per milliliter
Indications: For the treatment of bovine ketosis and as an anti-inflammatory agent in dogs, cats, horses, and cattle.

21CFR 522.540

Suitability Petition Action

Number: 03P-0523/CP1
Sponsor: Karen A. Sisson
Petition: Request permission to file an ANADA for a generic new animal drug ivermectin/praziquantel which differs from the pioneer product, ivermectin/praziquantel (Zimecterin® Gold Paste), Merial Ltd., NADA 141-214 by the following characteristics: The generic product will consist of a different dosage form (granule/crumble) from the pioneer.
Action: Filed on November 12, 2003.

Technical Amendment

The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed to provide for the safe use of formaldehyde to improve the handling characteristics of canola and soybean oilseeds and/or meals in feed for beef and dairy cattle, and to provide a description of the food additive. Section 573.460 of 21 CFR has been amended. This action is in response to a food additive petition filed by Rumentek Industries Pty Ltd. This rule is effective November 21, 2003.